Notice of Allowability	Application No.	Applicant(s)	
	10/760,625	DAVIS ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the application filed 1/20/04*.

2. ☒ The allowed claim(s) is/are *1-19*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Roland Norris on 9/14/05. The application has been amended as follows:

On line 3 of claim 19, "hematocrit value" was replaced with –hematocrit value (Hct)--;

On line 4 of claim 19, "100." was replaced with –100, wherein ρ_{bc} is the red blood cell density and ρ_{plasma} is the density of the plasma.--

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Regarding claims 1-12, 16, and 17, the prior art of record fails to teach or fairly suggest a method or apparatus for noninvasively measuring fluid density of a pulse flow system with non-rigid walls, wherein the fluid density ρ_b is calculated according to the generalized functional relationship

$$F\left(\frac{\rho_b v^2}{\Delta P}\right) = G\left(\frac{V_b}{\Delta V_b}, \frac{P}{\Delta P}\right)$$ or its derivatives, wherein

$\frac{V_b}{\Delta V_b}$ is a local relative fluid volume ratio, V_b being a basal volume of fluid in a vessel and ΔV_b being a volume change of the fluid in the vessel due to the pulse;

v is a fluid pulse propagation velocity; and

P is a basal fluid pressure and ΔP is a local change in fluid pressure.

US Patent No. 6,640,625 to Goodwin teaches a method and apparatus for measuring fluid density based on density, compressibility, and the speed of sound through a fluid (coil. 5, lines 46-53 of Goodwin) rather than based on measurements of a local fluid volume ratio, a fluid propagation velocity, the basal fluid pressure, and a local change in fluid pressure, as claimed by the instant application. Goodwin further fails to cite whether such method and device are suitable for determining fluid density of a pulse flow system with non-rigid walls.

US Patent No. 6,527,728 to Zhang teaches a method and device for measuring blood density in the body using an ultrasonic signal through the blood supply, wherein such ultrasonic signal reflects a volume measurement (col. 9, lines 6-20 of Zhang). However, the method and apparatus of Zhang fail to teach determining the blood density based on the local relative fluid volume ratio, the fluid pulse propagation velocity, the basal fluid pressure, and the local change in fluid pressure, as claimed by the instant application.

Regarding claims 13-15, the prior art of record fails to teach or fairly suggest an apparatus for noninvasively measuring fluid density of a pulsed flow system with non-rigid walls at a local measurement area comprising a calculator operable connected to

the pressure applicator and the impedance measurer for calculating a fluid density value of the local measurement area, in combination with all of the other limitations of the claim.

US Patent No. 6,128,518 to Billings et al., US Patent No. 4,875,488 to Shimazu et al., and "Electric impedance cuff for the indirect measurement of blood pressure and volume elastic modulus in human limb and finger arteries" by Shimazu et al. each teach a pressure applicator for applying external pressure to the local measurement area and an impedance measurer coextensive with the pressure applicator (fig. 1 of Billings; fig. 1 of Shimazu). However, none of the references teaches a calculator for calculating a fluid density value of the local measurement area that is operably connected to the pressure applicator and the impedance measurer.

Regarding claim 18, the prior art of record fails to teach or fairly suggest a method of noninvasively measuring a local relative fluid volume ratio $\frac{V_b}{\Delta V_b}$ in a pulsed flow system with non-rigid vessel walls by equating $\frac{Y_b}{\Delta Y_b} = \frac{V_b}{\Delta V_b}$, whereby the need to know the resistivity of the fluid in determining the local fluid volume ratio is eliminated, and wherein Y_b is the electrical admittance of the local basal fluid volume, ΔY_b is the electrical admittance change due to increased local volume from pulsed flow, in combination with all of the other limitations of the claim.

US Patent No. 4,875,488 to Shimazu et al. and US Patent No. 4,548,211 to Marks each teaches measuring impedance or admittance and a change in impedance or admittance and shows a relationship between a change in volume of the arm caused

by changes in the amount of the blood in the arm portion and admittance, wherein admittance is the reciprocal of impedance (col. 3, lines 20-23 and lines 42-59 of Shimazu; col. 1, lines 52-col. 2, line 27 of Marks; col. 7, line 22-col. 10, line 11 of Marks). However, both Shimazu and Marks fail to teach equating $\frac{Y_b}{\Delta Y_b} = \frac{V_b}{\Delta V_b}$, whereby the need to know the resistivity of the fluid in determining the local fluid volume ratio is eliminated, and wherein Y_b is the electrical admittance of the local basal fluid volume, ΔY_b is the electrical admittance change due to increased local volume from pulsed flow.

Regarding claim 19, the prior art of record fails to teach or fairly suggest a method of determining a hematocrit value (Hct) of blood wherein the hematocrit is determined according to the relationship $Hct = \frac{\rho_b - \rho_{plasma}}{\rho_{bc} - \rho_{plasma}} \times 100$ and where ρ_b is the density of the blood, ρ_{bc} is the red blood cell density, and ρ_{plasma} is the density of the plasma, in combination with all of the other limitations of the claim.

US Patent No. 6,740,036 to Lee et al. teaches a method wherein density of the blood is determined (col. 11, lines 39-47 of Lee) and a relationship between hematocrit, the density of blood, the density of plasma, and the red blood cell density (col. 8, line 65-col. 9, line 25 of Lee). However, Lee fails to teach determining the hematocrit value according to the relationship $Hct = \frac{\rho_b - \rho_{plasma}}{\rho_{bc} - \rho_{plasma}} \times 100$, where ρ_b is the density of the blood, ρ_{bc} is the red blood cell density, and ρ_{plasma} is the density of the plasma.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER
PRIMARY EXAMINER